

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.

Plaintiff,

V.

LUPIN LTD., LAURUS LABS LIMITED,
AND CIPLA LIMITED.

Defendants.

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) C.A. No. 22-615 (MN)
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**STIPULATION AND ORDER OF INFRINGEMENT OF CERTAIN CLAIMS AND
STIPULATION AND ORDER OF DISMISSAL OF CERTAIN CLAIMS AND
DEFENSES SPECIFIC TO CIPLA LIMITED**

Plaintiff Gilead Sciences, Inc. (“Gilead”) and Defendant Cipla Limited (“Cipla”), by their undersigned counsel, stipulate and agree, subject to the approval of the Court, as follows:

WHEREAS, Cipla has filed Abbreviated New Drug Application No. 216914, which ANDA references Gilead’s BIKTARVY® pharmaceutical product, with the United States Food and Drug Administration (“FDA”) seeking approval to make and sell a generic version of bicitgravir/emtricitabine/tenofovir alafenamide tablets EQ 50 mg base/200 mg/EQ 25 mg base (“Cipla’s ANDA Product”) prior to the expiration of U.S. Patent Nos. 9,708,342 (“’342 patent”), 10,385,067 (“’067 patent”), 10,548,846 (“’846 patent”), and 11,744,802 (“’802 patent”);

WHEREAS, Plaintiff filed the above-captioned suit against Cipla pursuant to 35 U.S.C. § 271(a), (b), (c), and (e)(2) alleging that Cipla’s submission of ANDA No. 216914 and/or the sale and use of Cipla’s ANDA Product constitute infringement of the ’342, ’067, ’846, and ’802 patents;

WHEREAS, Plaintiff's Count XXI of its Fourth Amended Complaint alleges Cipla has

infringed the '846 patent (*see* D.I. 203);

WHEREAS, Plaintiff's Count XXII of its Fourth Amended Complaint seeks declaratory judgment of Cipla's infringement of the '846 patent (*see* D.I. 203);

WHEREAS, Cipla alleges that the '846 patent is not infringed and is invalid (*see* D.I. 205);

WHEREAS, Plaintiff's Count XXIII of its Fourth Amended Complaint alleges Cipla has infringed the '802 patent (*see* D.I. 203);

WHEREAS, Plaintiff's Count XXIV of its Fourth Amended Complaint seeks declaratory judgment of Cipla's infringement of the '802 patent (*see* D.I. 203);

WHEREAS, Cipla alleges that the '802 patent is not infringed and is invalid (*see* D.I. 205);

WHEREAS, Gilead and Cipla seek to conserve their own and the Court's resources by narrowing the issues for discovery and trial in this case;

NOW THEREFORE, subject to the conditions and representations herein, Gilead and Cipla and their successors and assigns, by their undersigned counsel, hereby stipulate and agree, for the purposes of this litigation only, and will not contest before this Court or on appeal, as follows:

1. Pursuant to Rule 41(a) of the Federal Rules of Civil Procedure, all claims, counterclaims, and defenses as between Plaintiff and Cipla concerning the '846 patent are dismissed with prejudice;

2. Pursuant to Rule 41(a) of the Federal Rules of Civil Procedure, all claims, counterclaims, and defenses as between Plaintiff and Cipla concerning claims of the '802 patent other than claim 1 are dismissed with prejudice;

3. Cipla's submission of ANDA No. 216914 for Cipla's ANDA Product constitutes an act of infringement of claim 1 of the '802 patent under 35 U.S.C. § 271(e)(2), except to the extent such claim is held invalid or unenforceable or Plaintiff ceases to assert in this case;

4. Following final approval by the FDA, the sale, offer for sale, use, and/or manufacture within the United States, or importation into the United States, by Cipla of Cipla's ANDA Product covered by ANDA No. 216914 would constitute an act of infringement of claim 1 of the '802 patent by Cipla under one or more of 35 U.S.C. § 271(a), (b), or (c), except to the extent that such claim is held invalid or unenforceable or Plaintiff ceases to assert in this case;

5. Cipla will not assert in this case any defense of noninfringement of claim 1 of the '802 patent, will not assert that Cipla's submission of ANDA No. 216914 for Cipla's ANDA Product does not constitute an act of infringement of claim 1 of the '802 patent, and will not assert that the sale, offer for sale, use, and/or manufacture within the United States, or importation into the United States, of Cipla's ANDA Product covered by ANDA No. 216914 does not constitute an act of infringement of claim 1 of the '802 patent insofar as such claim is valid and enforceable or Plaintiff ceases to assert in this case;

6. Plaintiff and Cipla agree to the entry of this Order granting Plaintiff partial judgment on the issue of Cipla's infringement of claim 1 of the '802 patent consistent with the terms of this Order;

7. Plaintiff and Cipla shall each bear its own costs and attorney's fees with respect to the '846 patent and claims other than claim 1 of the '802 patent.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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July 21, 2025

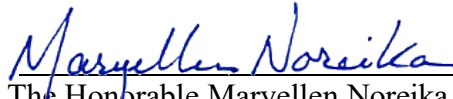
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Attorneys for Defendant Cipla Limited

SO ORDERED this 22nd day of July 2025.



The Honorable Maryellen Noreika
United States District Judge